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DRAFT MEETING MINUTES
March 22, 2012

Committee Member Present

Las Vegas: Adam Zold, Pharm.D.; Eveyln Chu, Pharm.D.; Shamim Nagy, MD; Weldon Havins, MD; Joseph Adashek, MD

Carson City: Kevin Desmond, RPh

Absent: Michael Hautekeet, RPh; David Chan, RPh; Constance Kalinowski, MD; Ronald Shockley, MD

Others Present

DHCFP:

Las Vegas: Coleen Lawrence, Chief Program Services; Kathy Stoner, Hearings and Policy Supervisor; Gabriel Lithier, Deputy Attorney General

Carson City: Mary Griffith, RN, Social Services Program Specialist

SXC Health Solutions

Las Vegas: Carl Jeffery, Pharm.D., Kevin Whittington, RPh

Carson City: Rob Earnest, Pharm.D., JD; Mariellen Rich, RPh, Irene Tobarak, SXC

HPES:

Carson City: Ed Arnold, PBM Liaison

Others:

Las Vegas: Bob Mull; Krystal Riccio, Roseman; Brandee Scholer, J&J; Lovell Robinson, Abbott; Tom O'Connor, Novartis; Tyler Allred, Pfizer; David Black, Shire; Eric Denenorf, Shire; Laura Litzenberger, Janssen Scientific Affairs; Sandy Sierawski, Pfizer; Eric Chancellor, Alcon; Brad Buecitahler, Elan; Bret Brewer, EMD Serono; Deborah Wafer, Gilead; Jeff Kurszawski, Covidien; Melissa Walsh, Novartis; Vic Benson, Merck; Efram Alton, Merck; Steve Fox, GSK; Shampa De-Oertel, Forest; Goeff Glen, Sunovion; Brooks Hubbard, BIPI; Bill O'Neill, BIPI; Megan Bender, Ascend Specialty Rx; Gil Astruc, Tarode; Matt Wessels, Sunovion; Paul Osterman, Roseman; Debra Bowersox, Roseman; Chansse Cajudoy, Roseman;

Andi Stratton, Vertex; Jamie Tobitt, Vertex; Brent Merritt, NNI; Soheyla Azizi, Eesai; Charissa Anne, J&J; Mike Ketcher, Novo; Chris Roberston, Novo; Mike Pinocci, Pfizer; Gena Grinestaff, Pfizer; Kris Dreues, Janssen

Carson City: Alex Lapasaran, Digestive Health Associates; Sabrina Aery, BMS; Sergey Zhuplaton, BMS; Jim Elowitt, Forest; Jeff Scheneman, Pfizer; Lori Honkwith, Bayer; Lisa Sheretz, American Lung; Chelsea Capurs, GCG

AGENDA

I. Call to Order and Roll Call

Meeting called to order at 1:11 pm by Dr. Nagy.

Ms. Lawrence addressed the Board Members and the Public. She stated today's meeting is a full agenda. She reminded the members and the public that this meeting agenda is robust due to some items that were a carry-over from last June's meeting. This is not a continuation, but some items were passed to the next meeting due to time constraints. The June 2011 meeting was the annual review that is required by statute, all drug classes on the PDL must be reviewed annually. Ms. Lawrence thanked Dr. Nagy for accepting the Chair of the Board position. She also extended a welcome to the new board members, Dr. Chu, Mr. Desmond, Dr. Zold and Dr. Shockley, and welcomed back the returning members. She explained that this committee is a complicated committee, but we have a very tried and true process. The process for each drug class is as follows: We allow public comment on that specific class, so please only address that drug class during the comment period. We have some ground rules for the comment period. Then our new vendor, SXC will give a clinical overview on that specific drug class. Next the committee will discuss and take action if the class of drugs is considered therapeutically equivalent. This is based upon the definition provided in the hand out that we have used since 2004 for "Therapeutic Alternative". Ms. Lawrence read the definition provided. After that action, the board may take into consideration circumstances for particular products for diagnosis, clinical indications and age. Next SXC will present to the committee their recommendations for drugs to be included on the PDL, that are in the best interest of the state. Previous to this meeting, a behind the scenes discussion resulted in these recommendations. But it is the Committee's education, experience, and clinical expertise that guides members to vote on items to be included on the PDL. Finally, the committee will make the final recommendation, it is key to know this because by statute, it is the board's authority that makes the PDL. The Board will decide what drugs are included on the PDL. If you have questions, the time for discussion is the time to ask. You may ask at any time, what is the system limitations, what can we do, what are the possibilities. You can add limitations by age, gender, age cohort, indication and we will help you by giving you ideas if asked what can be done with point of sale. Just ask, and we will let you know if it is feasible and what the system can do. And that is the final vote for what happens with the PDL.

Ms. Lawrence continued on the ground rules for all. This committee cannot consider cost at any time. At any time the conversation heads towards cost, myself or Mr. Lither will interrupt with a friendly reminder that we are not allowed to discuss, whether it is during the public comment period or during board discussion. Public comment today is limited to five minutes per person, company, or organization. Topics discussed during public comment are limited to the drug class and new materials only because we talk about these classes a lot. Please respect the committee members. They want to know what new information has come out since last update. According to the NRS, all anticonvulsants and certain diabetic products must be considered preferred. If we state that a certain product must be preferred, this rule will be cited. We're here to help with the process.

Mrs. Lawrence stated herself and Nevada Medicaid is very proud that this process is very transparent. Because of that a few points, we will stick to the agenda items, we cannot vote for items that are not on the agenda. We can't take actions which are not agendaized. You can make recommendations for future agenda items, but it must be included on today's agenda to discuss. All communications to the committee are public. We can't send emails to each other, you cannot discuss if you happen to meet at an occasion such as a doctor's meeting. Also, by statute, it takes a majority of the committee to vote affirmative to include an item on the PDL. So there are 10 members on the board, we have 6 present, so all committee votes must be unanimous today for an action item to carry. Ms. Lawrence reiterated the importance to not bring up costs.

II. Public Comment

None

III. Review and Approval of the June 23, 2011 Meeting Minutes

Dr. Nagy started with the review and approval of the June 2011 meeting minutes.

MOTION: Dr. Havins moved to accept the minutes.

SECOND: Dr. Adashek seconded the motion.

VOTE: Unanimous.

MOTION CARRIED

IV. Proposed New Drug Classes

A. Anticoagulants

1. Public Comment

Bill O'Neil, Quality Health Liaison with Boehringer Ingelheim, presented information about Pradaxa today. Mr. O'Neill reviewed indications, clinical and safety information in

the literature. Pradaxa was compared to open label warfarin in more than 18,000 patients. Some primary endpoints that are significant, is that Pradaxa 150mg twice daily significantly reduced the risk of ischemic, hemorrhagic stroke and systemic embolism by 35%. Intracranial hemorrhage was 59% lower with Pradaxa. The risk of myocardial infarction in patients receiving Pradaxa was numerically lower. Some primary safety endpoints: Pradaxa increases the risk of bleeding that can be significant and sometimes fatal. Lower total bleeds were seen with Pradaxa vs. warfarin. Higher rates of total GI bleeds with Pradaxa, 61% vs. 4% for warfarin. A lower rate of intracranial bleeds, 0.3% vs. 0.8% for warfarin. In patients 75 years or older, the risk of bleeding with Pradaxa may be greater. Mr. O'Neill reviewed the contraindications, risk factors of increased risk of bleeding. Increased effects are seen with renal dysfunction. No reversing agent is available, but it may be dialyzed, removal of about 60% of the drug in 2-3 hours, but data is limited at this time. Activated Prothrombin Complex Concentrates may be considered, but their use has not been evaluated. The dose should be reduced in renal impairment (CrCl of 30-50 ml/min) to 75mg bid. For severe renal impairment, use should be avoided.

Dr. Robert Mullen, local physician, explained the difficulties of treating some patients with warfarin. Giving a drug such as Xarelto is such a help to the patient, they don't have to stay in the hospital to get their INR in therapeutic value, they don't have to transfer to the warfarin clinic. Supports the once a day dosing of an anticoagulant that does not require monitoring is a big help.

Krystal Riccio, clinical faculty at Roseman University, who is currently practicing in a primary care office and Coumadin clinic, spoke of the challenges of managing a patient on Coumadin and what a relief it was to have products available with reduced monitoring requirements. Research has shown these products to be safe and effective. Ms. Riccio stated she thinks that having a prior authorization or other challenges in obtaining these medications provides difficulty in continuum of care. As a provider, she sees the challenges of transportation to the clinic as well as some drug interactions, talking just as an advocate from the patient's perspective. Dr. Adashek asked what medications she is proposing to be on the PDL. Dr. Riccio stated that these agents should be restricted to clinical indication, but she is speaking for rivaroxaban today since it has once daily dosing but believes they both have their use in therapy.

Laura Litzenberger with Janssen scientific affairs, spoke on behalf of Xarelto. Xarelto is a once a day anticoagulant, a direct Xa inhibitor. It has predictable pharmacokinetics and pharmacodynamics that require no monitoring. There are limited drug interactions, however drugs with strong PGP inhibitors 3A4 inhibitors should not be used. Xarelto has two indications, for the prevention of VTE in people who have undergone hip and knee replacement and also indicated for prevention of stroke in patients with non-valvular atrial fibrillation. In patients with non-valvular a-fib, the dose is 20mg once

daily, if CrCl is > 50ml/min, if 15-50 then 15mg. In patients that have undergone hip or knee replacement, the dose is 10mg once daily for 35 days after hip replacement or 14 days for knee replacement. In clinical studies for a-fib, Xarelto was shown to be non-inferior to warfarin, with similar rates of bleeding. Similar to Pradaxa, increased rates of bleeding were noted. In the hip and knee replacement studies, compared to enoxaparin and shown to be superior with similar rates of bleeding. Dr. Litzenberger referred the committee to www.xarelto.com for more information and the package insert.

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery addressed the Committee. He highlighted some of the clinical information. The DUR Board put clinical criteria on Pradaxa in the last meeting of 2011. Dr. Jeffery reviewed the PA criteria approved by the DUR board. Some of the drawbacks, are that there is no antidote and because there is no monitoring, it is difficult to assess patient compliance. Rivaroxaban does have the indication for the hip and knee replacement prophylaxis that gives it an edge over the dabigatran at this point. SXC said that these are therapeutically equivalent with each other and warfarin.

Ms. Lawrence reminded the committee that the DUR board is responsible for the clinical criteria and the P&T is responsible for the PDL. Each committee can refer topics to the other if they feel appropriate.

3. Committee Discussion and Action

MOTION: Dr. Havins moved to accept these products as therapeutically equivalent.

SECOND: Dr. Adashek seconded the motion.

VOTE: unanimous

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery suggested that warfarin, brand Jantoven and brand Coumadin be preferred, and the brand Xarelto and Pradaxa be non-preferred.

5. Committee Discussion and Approval of Drugs for inclusion on the PDL

MOTION: Dr. Adashek motioned to accept those recommendations, but add rivaroxiban to the preferred list as well.

SECOND: Dr. Havin's seconded the motion

DISCUSSION: Dr. Nagy asked for any discussion. Dr. Adashek explained in his line of work, there are advantages to Xarelto. There are challenges with monitoring for all medications and dialysis is a treatment for many medications in an overdose scenario. But this medication is clearly something that will help doctors and patients in the hospital and to have another medication available is long over-due.

VOTE: Unanimous
MOTION CARRIED

B. Bronchodilators for COPD

1. Public Comment

Dr. De-Oertel with scientific affairs for Forest Laboratories spoke on Daliresp. Daliresp is the first and only medication in the class of phosphodiesterase 4 inhibitors. It is indicated to reduce the risk of exacerbations in patients with severe COPD associated with chronic bronchitis. Many COPD exacerbations are often treated with systemic corticosteroids and often require hospitalization and may lead to death. Symptoms increase with severity and frequency as the disease progresses, patients typically experience 1-3 episodes per year and are particularly problematic for several reasons. They accelerate the decline of lung function, they worsen the quality of life, they have increased risk of hospitalization and mortality and are very expensive to treat, accounting for about 75% of the health care costs associated with the disease. Reducing the risk of exacerbations is a key goal of COPD treatment. While there are a number of treatments available, COPD patients continue to have exacerbations. That is why it is important to have additional treatment options available. The Mechanism of action is unique and works by selectively inhibiting an enzyme called PDE-4, which is found in lung cells and primarily responsible for metabolizing cAMP. The therapeutic effect of the drug is related to the fact that the accumulation of cAMP suppresses the activity of the inflammatory cells involved in the underlying pathophysiology of the disease. Efficacy, there are two trials with 3,100 patients, treatment with Daliresp reduced the rate of exacerbations by 17% compared to placebo. The number needed to treat to avoid 1 exacerbation per year was 5.29 and 3.64 patients respectively. There was also an effect on lung function. It has been shown to be effective when added to traditional therapies. Side effects were reviewed. Increases in psychiatric side effects are noted with this medication. Contraindicated in hepatic impairment and not recommended with CYP-450 inhibitors. The new guidelines recommend the use for severe disease along with traditional treatment. Ask that it be made preferred on the PDL. Dr. Adashek asked if this is a new class. Dr. Jeffery confirmed this will be a new class on the PDL.

Bill O'Neil provided a brief review of Spiriva. Dr. Jeffery interrupted and said the committee is only reviewing phosphodiesterase inhibitors at this time.

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery provided a brief overview of the medication. He highlighted the limitations of the medication. He said it's still not recommended for first or second line therapy. Dr. Havins asked if we are recommending to add it to the PDL. Ms. Lawrence explained to the Board that the DUR board will be reviewing for clinical criteria.

3. Committee Discussion and Action

DISCUSSION: Dr. Adashek stated that this product is in a class by itself. No vote is taken for therapeutic equivalence.

MOTION: Dr. Adashek motioned to add Daliresp to the PDL in a class by itself.

SECOND: Dr. Havins Second.

VOTE: Unanimous -

MOTION CARRIED

V. Established Drug Classes

A. Hepatitis C Agents

1. Public Comment

Jamie Tobitt of the Medical Affairs with Vertex Pharmaceuticals, talked in support of Incivek. The indications are for use in combo therapy usually. The SVR rate that is listed at 79% in the package insert is for naïve patients. Incivek is the preferred medication for the treatment of null responders with combo therapy. Mr. Tobitt referred to the package insert for drug-drug interactions and covered the side effects and treatment of a rash. For severe rash, therapy modifications should be considered. For other skin disorders such as Steven's-Johnson, all drugs should be stopped and the patient referred for medical treatment.

Vic Benson, family physician with Kaiser, now speaking for Merck for Victrelis. He covered the indications and effectiveness of Victrelis.. He stated he believed the effectiveness of the two drugs to be about the same. Victrelis may have an advantage on previous partial responders where it has been shown to be effective in short-course treatment, where with Incivek, you have to go with the long course. With anemia, the clinical trials with boceprevir allowed the use of EPO products where the telaprevir studies did not allow, so the dropout rate due to anemia was zero for the boceprevir

trials. Because of the way the clinical trials for the two products were set up and the different patient demographics used, it is difficult to compare the two agents, there are no head-to-head studies. The biggest difference is safety issues. Boceprevir does not have any indication to follow-up closely for rashes. There have been no incidents of serious rash. Pruritus and anal problems did not make the list of adverse effects for boceprevir. The biggest difference between the two is the hassle the provider and patient have to go through to manage the rash and pain, and there was dropout rate in the telaprevir group because of rash and not in the boceprevir trials. The chances of failure are less with the boceprevir group. In summary, both drugs are a great advancement in the treatment of Hepatitis C and are needed. The treatment results are tremendously improving the SVR rates and the treatment course. Both cause about the same amount of anemia. The biggest distinction is the skin affects, they didn't happen with the boceprevir trials.

Alex Lapasaran, Nurse Practitioner in Reno spoke on behalf of himself as a clinician and as a patient advocate. He stated that Hep C is a growing epidemic, becoming more of an epidemic than HIV and deaths from Hep C have surpassed deaths related to HIV. He cited higher success rates with protease inhibitors. He asked the committee that they keep unrestricted access to these life-saving medications.

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery gave a summary of this drug class review. He stated these are novel therapies that are important to have available. He referred to the summary pages in the binder. The PA criteria in the DUR minutes will be in effect in early April, following the recommendations from the manufactures. The differences have been highlighted. There may be a slight advantage with the telaprevir because of the shorter duration of treatment and has been shown to be effective for the null-responders. Dr. Jeffery stated they are essentially equivalent to each other.

3. Committee Discussion and Action

No discussion.

Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Havins moved that both drugs be considered therapeutically equivalent.

SECOND: Dr. Zold seconded the motion

VOTES: Unanimous

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

SXC recommended keeping Pegasys, Pegasys Convenient Pack, Peg-Intron and Redipen and Ribavirin as preferred and keep the remaining, including Incivek and Victrelis as non-preferred. Because this is part of the triple therapy and they require prior authorization, so there is no additional step to get either agent.

Dr. Adashek requests clarification. Dr. Jeffery restates that he believes they both should be non-PDL. Dr. Havins asked for reasoning behind this recommendation. Dr. Jeffery stated that making them non-PDL does not restrict their access. They still have clinical criteria, so there is a call to the call center already. Ms. Lawrence clarified the PA process. There is a clinical prior authorization based on DUR criteria. So the PDL criteria will already be part of that criteria. These two new drugs have been hitting for non-PDL criteria since last summer. We are recommending that we don't change anything. They are already meeting the criteria with the first call to the call center.

Dr. Havins asked if someone must fail therapy before they can get the non-preferred medications? Ms. Lawrence clarified that because approval of a non-PDL medication will be met by a unique indication of a non-preferred medication. Dr. Adashek asked if patients will be on this for the rest of their lives? Dr. Jeffery stated, no, these are short term treatment. Dr. Adashek asked what determines how long patients are on this? Dr. Jeffery stated, the viral load. Ms. Lawrence restated that the patients have been able to access these medications since they first came out using his criteria. Once they are finished, then 6 months later they check again and if zero viral load then they are considered cured.

Dr. Havins asked what was the disadvantage of these agents being on the PDL? Dr. Jeffery stated it is in the best interest of the State for them to remain off the PDL. Dr. Adashek asked if this is the polite way of saying this is a way to restrict for appropriate use? Dr. Jeffery and Ms. Lawrence both stated that is not the intention. Dr. Jeffery stated clinically they already need a prior authorization and will need to call into the call center. Providers will already have to call the call center. Dr. Adashek expressed confusion of why this class would be on the PDL in the first place. Ms. Lawrence stated the State collects supplemental rebates that go along with the PDL from the manufacturers. Dr. Havins asked for clarification that the State benefits more by not having these on the PDL? Dr. Adashek asked for clarification if the State gets a rebate if they are on or off the PDL. Ms. Lawrence stated there are negotiations all around the PDL. Ms. Lawrence stated again that the recommendation from SXC is for the best interest of the State, but the P&T Committee has the leeway to put whatever they want on the PDL, their decision is the final decision. Ms. Lawrence restated the fact that these medications are already considered non-preferred and they will require clinical PA.

Dr. Havins stated his concern, that we have evidence that there is a 45% cure rate with standard therapy, when we add these agents, it doubles or more the cure rate. Because of the vast difference in the cure rates, it would seem irresponsible not to have these drugs available. Ms. Lawrence reminded the members that there is still prior authorization criteria whether or not they are on the PDL. Dr. Adashek asked what is the purpose of the PDL? Ms. Lawrence stated the DUR board put clinical criteria on these products, so regardless of action taken today, there will still be clinical criteria to get these medications. Ms. Lawrence explained there is a separate function for the P&T committee for the PDL.

Dr. Jeffery asked if a high-level explanation of how the supplemental rebate process works would be permissible? Mr. Lither states that no, that would not be allowed. Dr. Adashek reinforced that it would seem irresponsible for the committee not to add at least one agent to the PDL given the cure rate for these products. He said that maybe they should recommend both be on the PDL because he is concerned with the perception of the board.

MOTION: Dr. Adashek motioned that both agents be included on the PDL.

SECOND: Dr. Havins seconded the motion for the purpose of discussion, because of the limited explanation of the recommendation and his lack of understanding.

Dr. Zold asked if the DUR Board can remove the clinical requirements. Dr. Jeffery and Ms. Lawrence confirmed that they could, but it would not seem logical since they are following the recommendation from the guidelines.

VOTE: Adashek - Aye, Chu – No, Nagy – Abstain, Havins – Abstain, Zold – Aye, Desmond – Abstain.

MOTION FAILS

Mr. Lither states that since six affirmative votes were not received, this motion does not pass. Dr. Adashek asked SXC if there is one medication preferred over the other. Dr. Jeffery stated that he believes telaprevir has a slight advantage, but reminded the committee that they already have an approved motion that they are equivalent. If he were to recommend one, he would say telaprevir.

MOTION: Dr. Adashek motioned that telaprevir be included on the PDL

SECOND: Dr. Havins Seconded.

VOTE: Adashek – Aye, Chu – No, Nagy – Aye, Havins – Aye, Zold – Aye, Desmond – Aye.

MOTION FAILS

Dr. Adashek asked Dr. Chu for her opinion of this class.

Dr. Chu asked why the DUR put clinical criteria on this class. Dr. Jeffery explained the criteria was added to assure appropriate use within the triple therapy and appropriate monitoring and duration of therapy. Dr. Chu clarified that this clinical criteria will always be in place regardless of their vote today. Dr. Jeffery confirmed this.

Ms. Lawrence invited the representative of the two manufactures to the speaker table. She explained the process the call center currently utilizes and how they are approved. New drugs within established classes automatically fall to the non-preferred status until they can be reviewed by the P&T Committee.

Dr. Havins asked the two representatives if it makes a difference to them if they are preferred or non-preferred? Both state yes, they would like to have their products on the PDL. Dr. Havins stated that in Las Vegas, they are seeing a high incidence of Hepatitis C and their action on the committee may be misinterpreted. Dr. Adashek stated that for the committee to agree to make both products non-preferred, goes against his better judgment. As a member of the committee and as a physician who treats patients with Hepatitis C, to vote for them both to remain non preferred makes a difference to him personally.

MOTION: Dr. Adashek motioned that telaprevir be made the preferred protease inhibitor for the treatment of Hepatitis C. His motion is they both be included on the PDL.

SECOND: Dr. Zold seconded the motion.

Mr. Lither expressed his concern that he doesn't want anyone to feel pressured to change their vote since they have voted on this same item already. He is concerned that the board may be seen as bullying for votes. He reminded the committee members that they should not feel pressured to vote one way and should not feel responsible because there are only six members of the board who could make it to the meeting.

VOTE: Adashek – Aye, Chu – Aye, Nagy – Abstain, Havins – Aye, Zold – Aye, Desmond –Aye.

MOTION FAILS

MOTION: Dr. Havins moved to make telaprevir the preferred product for this class.

SECOND: Dr. Nagy seconded the motion.

VOTE: Adashek – Aye, Chu – Aye, Nagy – Aye, Havins – Aye, Zold – Aye, Desmond –Aye.

MOTION CARRIED.

B. Cardiovascular: Angiotensin II Receptor Blockers and Diuretic Combinations

1. Public Comment

None

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery provided a brief overview. The only change is the addition of Edarbi. SXC believes Edarbi is therapeutically equivalent with the other agents in its class.

3. Committee Discussion and Action

Approve Clinical/Therapeutic Equivalency of Agents in Class

Dr. Chu asked if there is any morbidity or mortality information for Edarbi.

Dr. Jeffery explained that although these are important endpoints of a study, there is no information available at this time.

MOTION: Dr. Adashek motioned that they are all therapeutically equivalent.

SECOND: Mr. Desmond seconded the motion.

VOTE: Unanimous

MOTION CARRIED.

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended the preferred drug list remain the same and the new edition Edarbi remain non-preferred. The two preferred would remain losartan and Diovan, the rest remaining non-preferred.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Dr. Adashek motioned to accept the recommendations

SECOND: Dr. Chu seconded the motion

VOTE: Unanimous

MOTION CARRIED.

Dr. Jeffery stated that the combinations were not included in the above vote and will also need to be reviewed. Dr. Jeffery stated he believes all the products in this class are therapeutically equivalent.

MOTION: Dr. Zold motioned that these products are all considered therapeutically equivalent.

SECOND: Dr. Havins seconded the motion

VOTE: Unanimous

MOTION CARRIED

Dr. Jeffery recommended the PDL remain the same and Edarbyclor remain non-preferred.

MOTION: Dr. Chu motioned to keep the Edarbi combination as non-PDL.

SECOND: Dr. Zold seconded.

VOTE: Unanimous

MOTION CARRIED

C. Cardiovascular: Direct Renin Inhibitors and Combinations

1. Public Comment

None

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery gave a brief overview of combinations and standalone agents. He said there is one new agent available in this class, Tekamlo. Dr. Jeffery recommended that this class be considered therapeutically equivalent. Dr. Jeffery explained that this is a combination of Tekturna and amlodipine.

3. Committee Discussion and Action Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Havins motioned to accept Tekamlo as therapeutically equivalent within this class.

SECOND: Dr. Zold seconds

VOTE: Unanimous – Aye

MOTION CARRIED.

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended making Tekamlo preferred.

5. Committee Discussion and Approval of Drugs for inclusion on the PDL

MOTION: Dr. Havins made the motion to include Tekamlo on the Preferred Drug List.

SECOND: Dr. Adashek seconded the motion

VOTE: Unanimous

MOTION CARRIED

D. Diabetic Agents: Other Agents

1. Public Comment

Bill O'Neill spoke in support of Tradjenta. DPP-4 inhibitor, Mr. O'Neill reviewed indications and studies available in the package insert. No dose adjustment is needed for renal or hepatic impairment. Trajenta has not been studied in combination with insulin.

Michael Ketcher, pharmacist and medical liaison for Novo-Nordisk Asked that if their organization wants to remove or update the clinical PA criteria, that would be through the DUR Board. Ms. Lawrence confirmed this.

Sergey Zhuplatov, from BMS, spoke supporting Kombiglyze XR for the PDL.

Bill O'Neill from BI asked that Jentadueto be considered for the PDL as well. It is a combination product.

Ms. Lawrence clarified that the Statute states that drugs that were covered before June 30, 2010 are automatically included on the PDL.

Dr. Havins asks which drugs have been added since that date. Dr. Jeffery responded that that information will be covered in the next section.

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery provided summaries for five different classes. Drugs listed as non-preferred are Bydureon, Kombiglyze XR and Tradjenta that have come out since the last review of the PDL. Within their own classes, they are therapeutically equivalent.

3. Committee Discussion and Action

Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Havins moved that these drugs be considered therapeutically equivalent within their own classes.

SECOND: Dr. Adashek seconded the motion

VOTE: Unanimous

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended Kombiglyze XR and Tradjenta be included on the preferred drug list leaving the Bydureon as non-preferred. Bill O'Neil asked if Jentaduento is included? Dr. Jeffery states that that medication is already included on the preferred list.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Havins asked Dr. Jeffery why Bydureon is not recommended to be included. Dr. Jeffery responded that it is in the best interest of the State.

MOTION: Dr. Havins motioned that Tradjenta and Kombiglyze XR be included on the PDL.

SECOND: Dr. Adashek seconded the motion.

VOTE: Unanimous

MOTION CARRIED.

E. Ophthalmic Antihistamines

1. Public Comment

None

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery stated the new drug added to this class is Bepreve. He added that it is therapeutically equivalent to its peers. Currently the preferred list includes Alaway, Pataday, Patanol and Zaditor. Because Bepreve came out after the last review, it is considered non-preferred. Elestat, Lastacraft and Optivar all fall to the non-preferred list.

3. Committee Discussion and Action Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Havins moved that these be considered as therapeutic equivalents.

SECOND: Dr. Adashek seconded the motion

VOTE: Unanimous

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended that Bepreve be included on the PDL and the rest remain the same.

5. Committee Discussion and Approval of Drugs for inclusion on the PDL

MOTION: Dr. Adashek motioned to accept the recommendation

SECOND: Dr. Havins seconded the motion

VOTE: Unanimous

MOTION CARRIED.

F. Ophthalmic Non-Steroidal Anti-Inflammatory Agents

1. Public Comment

None

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery gave a brief overview of this established class. There were no new products to this class since last review. As it is now the PDL includes Acular, Diclofenac, Flurbiprofen, and Nevanac. Non-preferred include Acuvail and Bromday. Dr. Jeffery recommended these all be considered therapeutically equivalent.

3. Committee Discussion and Action Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Havins moved that these medications be considered therapeutically equivalent.

SECOND: Dr. Adashek seconded the motion

VOTE: Unanimous

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended this class remain unchanged.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Dr. Havins moved the class remain the same on the PDL

SECOND: Dr. Zold seconded the motion

VOTE: Unanimous

MOTION CARRIED

G. Ophthalmic Quinolones

1. Public Comment

None

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery gave a brief review of this established drug class. The new agents to this class include Moxeza and Besivance. Dr. Jeffery recommended products in this class be considered therapeutically equivalent.

3. Committee Discussion and Action

Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Adashek motioned that the board accept the recommendation for therapeutic equivalency.

SECOND: Dr. Zold seconded the motion

VOTE: Unanimous

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended ofloxacin and Moxeza be included in the preferred drug list and the rest remain unchanged.

5. Committee Discussion and Approval of Drugs for inclusion on the PDL

MOTION: Dr. Havins motioned that the board accept the recommendation and move Ofloxacin and Moxeza to the PDL and the others remain the same.

SECOND: Dr. Adashek seconded the motion

VOTE: Unanimous

MOTION CARRIED

H. Respiratory: Inhaled Corticosteroid/Beta-Adrenergic Combinations

1. Public Comment

A representative of Merck spoke about Dulera. He gave a brief overview of the product, and the studies. Trials had to show that adding a bronchodilator to the anti-inflammatory, but also had to show adding the anti-inflammatory to the bronchodilator was beneficial. The two trials had co-primary endpoints. Over 1500 patients were uncontrolled on conventional treatment. FEV1 is a bronchodilator measure. To test the effect of the anti-inflammatory, they take the trough of the FEV1, at the end of the duration of action of the bronchodilator. He stated all the endpoints showed improvement. Adverse events were reviewed, and similar to other products. This fixed dose combination was tested to a higher bar to be approved. He would like Dulera to be on the PDL.

Dr. Jeffery cited the letters that were submitted from practitioners supporting the availability of Dulera and one supporting the availability of Advair and Symbicort.

2. Drug Class Review Presentation – SXC Health Solutions

Dr. Jeffery gave a brief overview of the available products. He stated that we do not see an advantage of one over the other.

3. Committee Discussion and Action

Approve Clinical/Therapeutic Equivalency of Agents in Class

MOTION: Dr. Havins moved that the committee consider these three agents therapeutically equivalent.

SECOND: Dr. Adashek seconds the motion

VOTE: Unanimous –

MOTION CARRIED

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy

Dr. Jeffery recommended keeping the list the same with Advair and Symbicort as preferred and Dulera as non-preferred.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Adashek asked if there are head to head studies showing a benefit of the Dulera to the Advair. Dr. Jeffery cited the documents provided. Dr. Adashek recommended the

committee accept the recommendation and keep Advair and Symbicort as preferred and Dulera as non-preferred.

Dr. Havins asked if this suggestion is based on the feeling that Dulera has not been studied enough? Dr. Jeffery responded stating that it is in the best interest of the State.

Dr. Adashek asked if there is a benefit of having one available over another. Dr. Jeffery responded that having these two available is as good. And just because it is listed as non-preferred does not mean the recipient can never get this medication.

Dr. Havins asked how many requests for Dulera the call center has received. Dr. Jeffery stated he does not have this information available at this time. For the quarter, there have been seven claims for Dulera for the fee for service recipients. Ms. Lawrence clarified that the numbers do not include the MCO populations.

Dr. Havins asked for clarification that the seven prescriptions include that this is how many times a call was received and a PA granted. Dr. Jeffery confirmed that seven prescriptions were filled but we do not know how many requests were received.

Dr. Nagy requested that this drug be brought up again.

Dr. Adashek asked that the next time we present how many requests have been received for Dulera.

MOTION: Dr. Adashek motioned that this be tabled until the next meeting when the Prior Authorization numbers can be presented. He would like to see how many physicians are requesting this per month.

SECOND: Dr. Havins seconded the motion.

VOTE: Unanimous

MOTION CARRIED

VI. Report by SXC on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Dr. Jeffery gave a brief overview of the SXC information included in the back of the binder. Highlighting that generic Lexapro is now available. Some of the other drugs are not real big movers.

VII. Review of Next Meeting Location, Date, and Time

Next meeting is scheduled for June 28, 2012 at the same time.

VIII. Public Comment

None

IX. Adjournment

MOTION: Dr. Havins moved to adjourn the meeting.

SECOND: Dr. Nagy seconds

VOTE: Unanimous

MOTION CARRIED.

The meeting is adjourned at 3:25 PM.

DRAFT